K123372

510(k) Summary

JAN 14 2013

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Date of Preparation of this Summary:	January 3, 2013
Device Trade or Proprietary Name:	LipidMCC
Device Common/Usual Name or Classification Name:	Lipid Multiconstituent Calibrator
Classification Number/Class:	Class II / JIX (Calibrator, Multi-Analyte Mixture)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

Test Description:

This is an in vitro diagnostic product intended for use as a calibrator in clinical chemistry assays. Lipid Multiconstituent Calibrator (LipidMCC) contains Apolipoprotein A1, Apolipoprotein B, HDL-Cholesterol and LDL-Cholesterol in a lyophilized human serum-based matrix. The concentrations and activities are suitable for calibration of the Abbott ARCHITECT *c*8000. LipidMCC contains one level of the four analytes in a lyophilized human serum-based matrix.

All human sourced materials were tested and found to be non-reactive for HBsAg, anti-HBc, anti-HCV, HCV RNA or HCV Ag, anti HIV-1/HIV-2, HIV-1 Ag or HIV-2 RNA, anti-HTLV-1/2, and Syphilis by FDA-approved or equivalent methods.

Substantial Equivalence:

LipidMCC is substantially equivalent to the Apolipoprotein A1/Apolipoprotein B Calibrator (ApoA1/ApoB Calibrator) K983289. These calibrators yield substantially equivalent results on the ARCHITECT *c*8000 Analyzer. Device similarities and differences are summarized in Table I, Section I of this submission and are listed below:

Similarities:

- Calibrators use pooled human sera with constituents added as required to obtain component levels.
- Calibrators contain a single level of each analyte.
- Calibrators are lyophilized and stored at 2 to 8°C until expiration date.
- Calibrators are used in the calibration of the Apolipoprotein A1, Apolipoprotein B.
- Calibrators yield similar results.

Differences:

- LipidMCC is a single product that contains four analytes for calibration. TheApoA1/ApoB Calibrator is a single product that contains two analytes for calibration.
- LipidMCC is intended to be used to calibrate Apolipoprotein A1, Apolipoprotein B, HDL-Cholesterol and LDL-Cholesterol. ApoA1/ApoB Calibrator is intended for use to calibrate Apolipoprotein A1 and Apolipoprotein B assays only. The ApoA1/B Calibrator does not contain the HDL Cholesterol or LDL Cholesterol components.
- The reconstituted ApoA1/ApoB Calibrator is stable for 14 days at 2 to 8°C. Reconstituted LipidMCC is stable for 7 days at 2 to 8°C.

Intended Use:

For use in the calibration of the Apolipoprotein A1 (Apo A1), Apolipoprotein B (Apo B), Low Density Lipoprotein (LDL), and Ultra High Density Lipoprotein (UHDL) assays on the ARCHITECT *c*8000 clinical chemistry analyzer.

Performance Characteristics:

The standardization/traceability, value assignment and stability of the Lipid Multiconstituent Calibrator have been validated and verified following procedures approved by Abbott Laboratories, Inc.

A. Standardization/Traceability Information

LipidMCC traceability:

Analyte	Standard Material / Reference Method
HDL-Cholesterol	CDC described reference method for determination of HDL-cholesterol
LDL-Cholesterol	CDC described reference method for determination of LDL-cholesterol
Apolipoprotein A1	WHO/IFCC/CDC reference material (SP1-01)
Apolipoprotein B	WHO/IFCC/CDC reference material (SP3-08)

WHO—World Health Organization
IFCC—International Federation of Clinical Chemistry and Laboratory Medicine
CDC—Center for Disease Control and Prevention

Standardization Process

A master calibrator lot is used to assign values for each calibrator lot. The master calibrator lot was standardized against the respective reference materials and reference methods listed in the preceding table.

The standardization of the master calibrator lot to the HDL and LDL reference methods was achieved by a method comparison study in which human serum samples were analyzed:

- On an ARCHITECT *c*8000 instrument using the LipidMCC (preliminary assigned using on-market HDL and LDL Calibrators traceable to the CDC reference methods),

and

- Using CDC Reference methods performed by a CDC-certified CRMLN (Cholesterol Reference Method Laboratory Network) laboratory

Bias estimation based on the method comparison results was then used to adjust the LipidMCC HDL and LDL values in order to minimize bias to the respective reference methods.

The standardization of the master calibrator lot to the Apolipoprotein A1 and Apolipoprotein B reference materials was achieved by a protocol and standardization material kit (including the respective WHO/IFCC/CDC reference materials) obtained from the Northwest Lipid Metabolism and Diabetes Research Laboratories (University of Washington). [NOTE: This laboratory is the designated apolipoprotein standardization facility for the CDC Lipid Standardization Program (LSP)].

The standardization was based on calibration of an ARCHITECT *c*8000 instrument using the respective WHO/IFCC/CDC reference materials and analyzing the concentrations of Apolipoprotein A1 and Apolipoprotein B in the master calibrator lot. These values were then verified by a method comparison study using 40 serum samples with assigned reference values. The successful completion of this standardization process was documented in certificates received from the Northwest Lipid Metabolism and Diabetes Research Laboratories (University of Washington).

B. Value assignment

Value assignment is performed as follows:

- The testing is performed independently for each of the analytes, using one Abbott ARCHITECT *c*8000.
- For each analyte, the assay is calibrated using the master calibrator lot
- System suitability (validity) testing is performed by testing quality control samples with pre-defined ranges.
- Ten replicates of the test calibrator and of the master calibrator lot are tested (the 10 replicates include five replicates from each of two vials of calibrator).

- The mean analyte values and %CV are calculated for the master lot and for the test calibrator. The %CV for both lots should be ≤ 3%. The mean for the master lot should be within 3% of its target value. If these criteria are met, the mean for the in-process calibrator is the assigned value for this lot.

- The newly assigned values are verified by calibrating the system with both the master calibrator lot and with the newly assigned calibrator, and testing pre-assigned control samples (typically a previously assigned calibrator lot).

- Acceptance criteria: the mean concentration for the control sample using the test calibrator must be within 5% of the mean concentration using the master lot calibrator and also within 5% of the pre-assigned value.

C. Shelf-life Stability

Testing was performed for three lots of calibrator.

Vials from each lot of the lyophilized calibrator were stored at the designated storage temperature (2 to 8°C) and at -80°C. Pairs of vials (one from each of the two storage conditions) were opened, reconstituted, and tested at eight designated time points up to 190 weeks (3.6 years). Percentage deviations were calculated for the vial stored at 2 to 8°C from the corresponding vial stored at -80°C.

Results:

Results for all three calibrator lots passed the criteria of up to ± 5% deviation at all time points. There was one exception: Lot 046RDLP at 52 weeks, there was 6.2% difference for LDL, but all results passed at 56 weeks and all subsequent time points.

Conclusion:

The shelf-life stability data supports stability of LipidMCC for 190 weeks (3.6 years) at 2 to 8°C. Based on this study, the claimed shelf-life stability is 36 months (3 years).

D. Open Vial Stability

Testing was performed for three lots of lyophilized calibrator.

Sets of three vials each from each lot of the lyophilized calibrator were opened, reconstituted, and stored for 7 and 10 days at 2 to 8°C. Another set of three vials were reconstituted and opened daily (for 10 days). All stored samples were tested along with a freshly reconstituted calibrator (control) at the beginning and end of the run. Percentage deviations were calculated from the fresh calibrator at the start of the run. Controls were also tested at the start and end of the run and compared to target.

Results for all three calibrator lots passed the criteria of up to ± 5% deviation comparing to the fresh calibrator for all analytes (HDL, LDL, Apo A1, Apo B). LipidMCC is stable for 10 days when stored at 2 to 8°C, reconstituted, and opened daily. Based on this study, the claimed open vial stability at 2 to 8°C is seven days.

Conclusion:

LipidMCC is substantially equivalent to the Apolipoprotein A1/Apolipoprotein B Calibrator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 14, 2013

Abbott Laboratories
c/o Linda Morris
1921 Hurd Dr.
Irving, TX 75038

Re: k123372
Trade/Device Name: Lipid Multiconstituent Calibrator (LipidMCC)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator, Multi-Analyte Mixture
Regulatory Class: Class II
Product Code: JIX
Dated: October 31, 2012
Received: December 4, 2012

Dear Ms. Linda Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Katherine Serrano

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123372

Device Name: Lipid Multiconstituent Calibrator (LipidMCC)

Indications for Use:

Abbott Lipid Multiconstituent Calibrator is an in vitro diagnostic product intended for the calibration of Abbott Apolipoprotein A1, Apolipoprotein B, HDL-Cholesterol and LDL-Cholesterol assays on the ARCHITECT c8000 clinical chemistry analyzer.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123372